

human use among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission and European Medicines Agency; International Federation for Animal Health—Europe; FDA; the U.S. Department of Agriculture; the U.S. Animal Health Institute; the Japanese Ministry of Agriculture, Forestry, and Fisheries; and the Japanese Veterinary Products Association.

Six observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, one representative from the industry in Canada, one representative from the government of South Africa, and one representative from the industry in South Africa. The VICH Secretariat, which coordinates the preparation of documentation, is provided by HealthforAnimals.

## **II. Guidance for Industry on Studies To Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach To Establish an Acute Reference Dose**

In the **Federal Register** of June 1, 2015 (80 FR 31041), FDA published the notice of availability for a draft guidance entitled “Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose” (VICH GL54) giving interested persons until July 31, 2015, to comment on the draft guidance. FDA received two comments on the draft guidance, and those comments, as well as those received by other VICH member regulatory agencies, were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated June 1, 2015. The final guidance is a product of the Safety Expert Working Group of the VICH.

This VICH guidance document is intended to address the nature and types of data that can be useful in determining a toxicological ARfD for residues of veterinary drugs, the studies that may generate such data, and how

the ARfD may be calculated based on these data.

## **III. Significance of Guidance**

This guidance, developed under the VICH process, is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). For example, the document has been designated “guidance” rather than “guideline.” In addition, guidance documents must not include mandatory language such as “shall,” “must,” “require,” or “requirement,” unless FDA is using these words to describe a statutory or regulatory requirement.

The guidance represents the current thinking of FDA on “Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This is not a significant regulatory action subject to Executive Order 12866.

## **IV. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

## **V. Electronic Access**

Persons with access to the Internet may obtain the guidance at either <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <https://www.regulations.gov>.

Dated: August 18, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017–17872 Filed 8–22–17; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA–2017–D–1956]

## **Identifying Trading Partners Under the Drug Supply Chain Security Act; Draft Guidance for Industry; Availability**

### *Correction*

Notice document 2017–17569, appearing on pages 39589 through 39590, in the issue of Monday, August 21, 2017, was published in error. It should be removed.

[FR Doc. C1–2017–17569 Filed 8–22–17; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

## **National Institute of Child Health and Human Development Meetings; Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Child Health and Human Development Initial Review Group Health, Behavior, and Context Subcommittee.

*Date:* October 16–26, 2017.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Kimberly L. Houston, MD, Scientific Review Officer, Eunice Kennedy Shriver National Institute of Children Health and Human Development, 6701B Rockledge Drive, Room 2127B, Bethesda, MD 20892, 301–827–4902, [kimberly.houston@nih.gov](mailto:kimberly.houston@nih.gov).

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel; NICHD International and Domestic Pediatric and Maternal HIV and Other High Priority Infectious Diseases Data Coordinating Center.

*Date:* October 18, 2017.